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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

NEAL, TIMOTHY J

ART UNIT	PAPER NUMBER
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3731

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/05/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

58

Office Action Summary	Application No. 10/776,457	Applicant(s) KONSTANTINO ET AL.	
	Examiner Timothy J. Neal	Art Unit 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 October 2006.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15, 17-20, 54 and 55 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1-15, 17-20, 54 and 55 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>7/06 8/06</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This action is in response to Applicant's amendment received on 10/30/2006. The Examiner acknowledges the two new IDS's filed on 7/20/2006 and 8/28/2006. Claims 1-15, 17-20, 54, and 55 are pending in this application. Claims 16, 21-53 and 56-73 have been cancelled. Claims 22 and 23 are shown as being cancelled and amended, however, they have not been amended properly and were withdrawn from consideration as being drawn to a non-elected group. The Examiner will not consider these two claims.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 20 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claim recites, "wherein the scoring element is not secured to an outer surface of the balloon." The Examiner considers this new matter because the specification in paragraphs 15 and 55 discloses that the scoring element is generally and preferably secured to the balloon. The specification does state

Art Unit: 3731

that the scoring element is not necessarily attached to the balloon, being that it may be attached to the catheter and not the balloon (Paragraph 57). However, where the scoring element is attached is not the same as where it is secured. The device, as understood by the Examiner, is secured to the balloon by flaps or lobes to shield the scoring element until inflation of the balloon. The word "secured" is not synonymous with "attached". In all embodiments disclosed, the Examiner considers the scoring element to be secured to the outer surface of the balloon by either the flaps or lobes of the balloon. Furthermore, claim 20 depends from claim 15, which recites that the scoring element is located within the helical recess. This helical recess helps to secure the scoring element to the balloon.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-6 are rejected under 35 U.S.C. 102(e) as being anticipated by Pallazza (US 2003/0083687).

Pallazza discloses a catheter (Item 108) and a radially expansible balloon having a permanent fold line extending helically around the balloon (Fig 11B). Furthermore,

Art Unit: 3731

the number of fold lines and their relative location is shown in Fig 11B. The groove and crease are considered to be substantially equivalent to the pleat described in Paragraph 91.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pallazza (US 2003/0083687) in view of Tsukashima et al. (US 5,350,361)

Should Applicant argue that the fold lines of Pallazza are not permanent or formed prior to folding, the Examiner is providing a rejection on the grounds of obviousness. Tsukashima teaches that permanent fold lines allow the balloon to collapse upon deflation into the desired, predetermined shape (Col 3 Lines 25-45). Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Pallazza's folds to include Tsukashima's permanent lines. Such a modification would cause the balloon to symmetrically deflate.

Furthermore, the flaps and lobes of claims 7 and 8 are described in both Pallazza (Paragraph 2) and Tsukashima (Col 2 Line 5) in order to minimize the profile of the balloon.

Claims 9-15 and 17-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pallazza (US 2003/0083687) in view of Shiber (U.S. 2002/0151924).

Pallazza discloses the invention substantially as claimed as stated above. Pallazza does not disclose a scoring structure. Shiber teaches a scoring structure (Item 92) to engage an obstruction in a vessel. Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Pallazza's balloon to include Shiber's scoring element. Such a modification would provide a means to engage an obstruction in a vessel. Furthermore, aligning the scoring element with the helical fold line would be obvious in order to shield the scoring elements until inflation.

Regarding independent claim 15, Pallazza discloses the structure of the balloon including the groove and recess. The recess is formed when the balloon is folded with the wings, flaps, or lobes as stated in the reference. The scoring element of Shiber would be placed in this recess. The Shiber reference discloses the scoring element placed in a recess (Fig 7) so it would be obvious to place the element in the helical recess of Pallazza.

The limitations of the other dependent claims are found in Fig 7 and Paragraph 39.

Claims 9-15 and 17-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pallazza (US 2003/0083687) in view of Tsukashima et al. (US 5,350,361) further in view of Shiber (U.S. 2002/0151924).

This rejection is provided should the Applicant argue the Pallazza reference lacks permanent fold lines. Pallazza and Tsukashima disclose the invention substantially as claimed as stated above. They do not disclose a scoring structure. Shiber teaches a scoring structure (Item 92) to engage an obstruction in a vessel. Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Pallazza and Tsukashima's balloon to include Shiber's scoring element. Such a modification would provide a means to engage an obstruction in a vessel. Furthermore, aligning the scoring element with the helical fold line would be obvious in order to shield the scoring elements until inflation.

Regarding independent claim 15, Pallazza and Tsukashima disclose the structure of the balloon including the groove and recess. The recess is formed when the balloon is folded with the wings, flaps, or lobes as stated in the references. The scoring element of Shiber would be placed in this recess. The Shiber reference discloses the scoring element placed in a recess (Fig 7) so it would be obvious to place the element in the helical recess of Pallazza.

Claims 54 and 55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pallazza (US 2003/0083687) in view of Miyagawa et al (US 6,468,243).

Pallazza discloses the invention substantially as claimed as stated above. Pallazza does not disclose the method of using the balloon catheter as claimed. Miyagawa teaches inserting the catheter in its helically-folded state into the body lumen;

Art Unit: 3731

advancing the catheter to a treatment site within the lumen; and inflating the balloon to engage a wall of the lumen to treat the lumen (Col 3 Lines 24-33).

Regarding claim 55, Miyagawa et al. discloses deflating the balloon so that the at least one fold collapses into the helically compressed state to disengage the wall of the lumen; and removing the catheter from the lumen (Col 3 Lines 30-33).

Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Pallazza's balloon to include Miyagawa's method of treating a body lumen. Such a modification would be useful for treatment of a vessel.

Claims 54 and 55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pallazza (US 2003/0083687) in view of Miyagawa et al (US 6,468,243) further in view of Tsukashima et al. (US 5,350,361).

This rejection is provided should the Applicant argue the Pallazza reference lacks permanent fold lines. Pallazza and Tsukashima disclose the invention substantially as claimed as stated above. They do not disclose the method of using the balloon catheter as claimed. Miyagawa teaches inserting the catheter in its helically-folded state into the body lumen; advancing the catheter to a treatment site within the lumen; and inflating the balloon to engage a wall of the lumen to treat the lumen (Col 3 Lines 24-33).

Regarding claim 55, Miyagawa et al. discloses deflating the balloon so that the at least one fold collapses into the helically compressed state to disengage the wall of the lumen; and removing the catheter from the lumen (Col 3 Lines 30-33).

Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Pallazza and Tsukashima's balloon to include Miyagawa's method of treating a body lumen. Such a modification would be useful for treatment of a vessel.

Response to Arguments

Applicant's arguments with respect to claims 1-20, 54, and 55 have been considered but are moot in view of the new ground(s) of rejection.

The Applicant amended the claims so that the helical fold lines must be present from the proximal to the distal end of the balloon. The Hijlkema reference did not anticipate the new claim. However, the Examiner considers the Pallazza reference alone or in combination with the Tsukashima reference to read on the claim. These references disclose permanent fold lines so that the balloon may refold along these lines upon deflation. The Examiner notes that helically folded balloons are known to be used in the art to reduce the diameter of the catheter. The Tsukashima reference teaches the desirability of making permanent fold lines within the balloon surface so that the balloon will symmetrically and predictably refold. Therefore, the Examiner considers it within the purview of a person having ordinary skill in the art to make permanent helical fold lines in a balloon so that both advantages will be present. The groove of claim 15 is met by the cited references. Pallazza teaches pleats along the helical fold that is substantially equivalent to a groove. Also, the Examiner notes that both

Art Unit: 3731

references, Pallazza and Tsukashima, disclose folding balloons to form wings, flaps, or lobes. These features create the recess. Also, the Shiber reference discloses placing the scoring elements within a recess so that the element is shielded until inflation of the balloon. Therefore, the Examiner considers the modifications required to meet the claims to be within the purview of a person having ordinary skill in the art and to be suggested by the references. Miyagawa recites the steps of the method. Miyagawa lacks the structure of the claims. Pallazza and/or Tsukashima provide the structure of the method claims rendering them obvious. Furthermore, the Examiner considers it to be within the purview of a person having ordinary skill in the art to use a balloon catheter in the manner claimed. In conclusion, the Examiner considers the claims to either be anticipated or rendered obvious by the prior art.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

Art Unit: 3731

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Timothy J. Neal whose telephone number is (571) 272-0625. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TJN


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SUPERVISORY PATENT EXAMINER
12/22/06